

SPL Pharma Subteam Electronic Drug Listing/Establishment Registration Lifecycle Team Meeting Minutes – January 20, 2010

Introduction & Welcome of New Team Co-Leaders

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Team distribution list is being transitioned, so apologies for any duplications in the interim.

Update on Leadership Team

- A review of Dailymed revealed that only 70% of the labels that have Medication Guides are compliant with proper posting. Leadership team is proposing that FDA initiate a validation to aid compliance.

- Exploring other situations where it would be helpful to have consistent data and associated validation rules.

Update on the delisting meeting with DRLS staff (separate specific minutes to follow)

Jean Kirkeleit-Davis, Hospira, led a collaborative meeting with FDA to review delisting issues and proposals (see 12/8/09 minutes for proposal details).

Goal of meeting – to dialogue and create delisting process that is mutually agreeable for FDA and time effective for industry, eliminating non value added work. FDA is aware of the issue is in the process of simplifying delisting. Pat and Jean will continue to monitor this and bring updates to the team.

Note: DRLS can provide list of NDC codes that are drug listed by request. Email: drls@fda.hhs.gov

FDA Validation & SPL R4 MANUAL Overrides

Currently, it is our understanding that SPL R4 files are failing FDA validation for *any changes* in the metadata, and manual override is required. The reason is that FDA assumes these are new products. Because Industry provides drug listing when updates occur, metadata changes are common from version to version (especially around new UNII codes, or further information in alignment with SPL guidelines as knowledge is gained).

This process places a burden on Industry and FDA to resolve manually each time. This issue will be added to Q&A list, and suggestion to explore further with Process Team and FDA.

It was also noted that FDA is now cross checking R3 to R4 metadata changes and tightening validation.

Action: Pat to send note to Terri to place on Q&A list.

Changing a physical characteristic

Scenario: retaining the NDC number (Product Number debossed on tablet will remain consistent with current NDC number), however, changing the product characteristics of an solid dosage form image that currently exists in SPL v3 and will be changed in SPL v4 (changing tint of color and shape)?

Suggest CMC input whether this is a real product change and whether FDA will view as such.

SPL R4 Tip:

New validation rule and instructions related to state and zip code in metadata: for non-US sites, FDA suggests placing dashes "-" in those fields.

Please Note: FDA's process is to treat Gateway test files, if valid, as real submission. Do not believe this has been documented previously.